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zimmer spine

510(k) SUMMARY
Universal Clamp® Spinal Fixation System
510(k) Number K110348

Date of Summary Preparation: August 3, 2011

Submitter:
Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Company Contact:
Elsa A. Linke
Regulatory Affairs

Manufacturer:
Zimmer Spine
Cité Mondiale
23 Parvis des Chartrons
33080 Bordeaux
France

Device Name: Universal Clamp® Spinal Fixation System

Common Name: Spinal Fixation System

Classification Name: Bone Fixation, Cerclage

Product Code: OWI

Regulation Number: 21 CFR 888.3010

Device Classification: Class II

Predicate Devices:
Universal Clamp® Spinal Fixation System K091190, K081622, K060009
DePuy AcroMed ISOLA System K962984
Medtronic CD Horizon Spinal System K091445
Synthes USS Small Stature K994121
Luque Segmental Spinal Instrumentation K913561

Description of Device:

The Universal Clamp® Spinal Fixation System is a temporary orthopedic implant intended to provide stabilization during the development of solid bony fusion and aid in the repair of bone fractures. The device system is designed to be incorporated into constructs and used in conjunction with other medical device implants made of either stainless steel or titanium whenever "wiring" may help secure the attachment of other implants.

The Universal Clamp® is available in both stainless steel and titanium versions. The stainless steel clamp is available in 3 sizes: 5.5, 6.0 and 6.35mm. The titanium clamp is available in 2 sizes of 5.5 and 6.0 mm. The different sizes are designed for compatibility with rods of the same sizes. A woven polyester band and locking screw are also provided.

Intended Use:

The Universal Clamp® Spinal Fixation System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Universal Clamp® Spinal Fixation System may also be used in conjunction with other medical implants made of similar metals whenever "wiring" may help secure the attachment of other implants.

Comparison of Technological Characteristics:

The Universal Clamp® Spinal Fixation System is like the predicate devices in that through segmental fixation it stabilizes the spine as an adjunct to fusion in the correction of spinal deformities.

Substantial Equivalence:

A review of the clinical literature establishes that the Universal Clamp® Spinal Fixation System is substantially equivalent to the predicate devices in its safety and effectiveness profile in the treatment of pediatric scoliosis patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine, Inc.
% Ms. Elsa Linke
7375 Bush Lake Road
Minneapolis, Minnesota 55439

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Re: K110348
Trade/Device Name: Universal Clamp® Spinal Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: August 03, 2011
Received: August 04, 2011

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110348

Device Name: Universal Clamp® Spinal Fixation System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110348